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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/067,980	02/08/2002	Dan Gazit	P-4891-US1	9918

27130 7590 01/28/2004

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EXAMINER	
NGUYEN, QUANG	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 01/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/067,980	GAZIT ET AL.	
	Examiner	Art Unit	
	Quang Nguyen, Ph.D.	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-63 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-63 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-63 are pending in the present application, and they are subjected to the following election/restrictions.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, drawn to a method of enhancing repair of a cartilage or of inducing formation of a cartilage, said method comprises the step of administering to a subject an effective amount of a cell which expresses at least one factor of the T-box family, classified in class 424, subclass 93.1.

II. Claims 11-18 and 48-52, drawn to a method of enhancing repair of a cartilage or of inducing formation of a cartilage in the body, said method comprises the step of administering a recombinant vector which comprises a nucleic acid encoding a factor of the T-box family to the cartilage of a subject, and a composition comprising at least one recombinant vector which comprises a nucleic acid sequence encoding at least one factor of the T-box family and a pharmaceutically acceptable carrier, classified in class 514, subclass 44.

III. Claims 19-22, drawn to a method of inducing chondrocyte differentiation comprising the step of administering of a recombinant vector which comprises a nucleic acid encoding a factor of the T-box family, thereby

inducing chondrocyte formation, can not be classified because the claims are incomplete.

IV. Claims 23-29 and 42-47, drawn to a method of repairing or forming a cartilage in a subject in need comprising the steps of: obtaining a cell from the subject, transfecting said cell with a recombinant vector comprising a nucleic acid sequence encoding a factor of the T-box family, so as to obtain an engineered cell which expresses a factor of the T-box family; and administering said engineered cells to the subject, and a composition comprising an engineered cell which expresses a factor of the T-box family and a pharmaceutically acceptable carrier; classified in class 424, subclass 93.2.

V. Claims 30-41, drawn to a method for the production of a transplantable cartilage matrix comprising the recited steps in claim 30, and an engineered cell which expresses a factor of the T-box family, classified in class 435, subclasses 455, 325.

VI. Claims 53-57, drawn to an implant device comprising at least one engineered cell which expresses a factor of the T-box family and a pharmaceutically acceptable carrier, classified in class 424, subclass 422.

VII. Claims 58-61, drawn to a method of suppressing cartilage formation, comprising the step of administering to a subject in need an antagonist to a factor of the T-box family thereby suppressing cartilage formation,

wherein the antagonist is an antibody, classified in class 424, subclass 130.1.

VIII. Claims 58-61, drawn to a method of suppressing cartilage formation, comprising the step of administering to a subject in need an antagonist to a factor of the T-box family thereby suppressing cartilage formation, wherein the antagonist is an antisense, classified in class 514, subclass 44.

IX. Claims 58-61, drawn to a method of suppressing cartilage formation, comprising the step of administering to a subject in need an antagonist to a factor of the T-box family thereby suppressing cartilage formation, wherein the antagonist is a protein, classified in class 514, subclass 2.

X. Claims 58-61, drawn to a method of suppressing cartilage formation, comprising the step of administering to a subject in need an antagonist to a factor of the T-box family thereby suppressing cartilage formation, wherein the antagonist is a nucleic acid, classified in class 514, subclass 44.

XI. Claims 58-61, drawn to a method of suppressing cartilage formation, comprising the step of administering to a subject in need an antagonist to a factor of the T-box family thereby suppressing cartilage formation, wherein the antagonist is a carbohydrate, classified in class 514, subclass 23.

XII. Claims 62-63, drawn to a method of screening candidate nucleic acid sequence which is involved in the early stages of cartilage development having the steps recited in claim 62, classified in class 435, subclass 6.

Claims 58 and 60-61 link patentably distinct inventions of Groups VII to XI that lack unity of invention. This is because an antagonist to a factor of the T-box family comprising an antibody, an antisense, a protein, a nucleic acid and a carbohydrate, all of which are chemically distinct products that have no substantial common structural elements one from the others. Additionally, as set forth in MPEP 803.02, unity of invention exists if all species recited in a claim (1) shows a common utility, **and** (2) share a substantial structural feature disclosed as being essential to that utility.

Upon the allowance of the linking claims, the restriction requirement as to the linked invention shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims or the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-132(CCPA 1971). See also MPEP 804.01.

The above inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I to V and VII-XII are distinct methods involving different starting materials, different method steps, and different desired end results, and therefore they require different technical considerations for achieving the desired end-results. For example, the method of Group I does not require the use of any engineered cell expressing at least one factor of the T-box family to enhance repair or to induce formation of a cartilage in a subject; the method of Group II is drawn to an *in vivo* gene therapy method for enhancing the repair or inducing formation of a cartilage in the body of a subject; the method of Group IV is an *ex vivo* gene therapy method for repairing or forming a cartilage in a subject; the method of Group V is drawn simply to a method for the production of a transplantable cartilage matrix; the methods of Groups VII to XI are drawn to a method of suppressing cartilage formation in a subject using chemically distinct antagonists to a factor of the T-box family comprising an antibody, an antisense, a protein, a nucleic acid and a carbohydrate, respectively; the method of Group XII is directed to the screening candidate nucleic acid sequence which is involved in the early stages of cartilage development. As written, the method of inducing chondrocyte differentiation of Group III is incomplete, and therefore the Examiner is uncertain what exactly Applicants intend to claim.

The implant device of Group VI is not required for the use of any of the methods of Groups I to V and VII-XII. The composition comprising at least one recombinant vector of the present invention and a pharmaceutically acceptable carrier of Group II is

distinct from the composition comprising an engineered cell expressing a factor of the T-box family and a pharmaceutically acceptable carrier of Group IV or an engineered cell which expresses a factor of the T-box family of Group V, and that it is not required for any of the methods of Groups I, III-V and VII-XII. Similar reasons can be applied for the compositions of Groups IV and V.

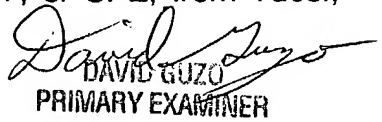
Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and separate search requirements, it would be unduly burdensome for the examiner to search and/or consider the patentability of all of the inventions in a single application. Therefore, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17 (h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, David Guzo, Ph.D., may be reached at (571) 272-0767, or SPE, Irem Yucel, Ph.D., at (571) 272-0781.



DAVID GUZO
PRIMARY EXAMINER